REMARKS

Claims 1-4, 8 and 19 are pending in the application. Claim 109 has been added. Claims 1 and 19 are currently amended. The claim amendments and the new claim are supported throughout the specification. For example, the claim amendments and new claim are supported by paragraphs [0011], [0012], [0145], and [0196] of the published application US 2005/0196817 A1. No new matter has been presented.

Reconsideration of the application in view of the current claims and further in view of the following remarks is respectfully requested.

I. DOUBLE PATENTING REJECTION

Claims 1-4, 8 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims in US application Nos 11/543,312, 11/690,767 and 11/770,608.

Applicants will address this issue and file a terminal disclaimer should the claims be deemed allowable.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 1-4, 8 and 19 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Applicants respectfully traverse this rejection. However, in order to expedite prosecution without acquiescing to Examiner's rejection, claim 1 has been amended.

Amended claim 1 is described in sufficient detail in the specification such that one skilled in the art can reasonably conclude that Applicants had possession of the claimed invention. As summarized in the MPEP § 2163, "[t]he first paragraph of 35 U.S.C. § 112 requires that the 'specification shall contain a written description of the invention ...' This requirement is separate and distinct from the enablement requirement. See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991)". The section goes on to provide that "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor

had possession of the claimed invention." Thus, the issue is whether the original application provides adequate support for the claims. Id.

The claims and specification of the instant application do provide ample written description for the pending claims. Claim 1 recites "comparing the concentration of each said analyte(s) to a corresponding reference concentration selected to indicate the presence or absence of severe sepsis", "provided that at least one of said analyte(s) is myeloid progenitor inhibitory factor-1 ("MPIF-1")", and "wherein an elevation in the concentration of said analyte(s) in the test sample of about two fold relative to the reference concentration is indicative of the presence of severe sepsis in the human". The concept that sepsis is diagnosed in a human subject if the concentration of at least one analyte is elevated relative to a reference sample is fully described in the specification, for example, in paragraphs [0011] – [0020]. These paragraphs described both MPIF-1 and TNF-R1. For instance, paragraph [0011] states "[s]epsis is diagnosed in the human subject if the concentration of the at least one analyte is elevated in the test sample relative to the reference range for the control sample".

In addition, that an elevation in the concentration of an analyte(s) in the test sample of about two fold relative to the reference concentration is indicative of the presence of severe sepsis in the human is fully described, for example, in paragraphs [0145] and [0196] of the published application. For instance, in paragraph [1045] the specification states "[o]nly analytes that fulfilled the following criteria were evaluated as possible sepsis markers: ... (2) there should be at least a two fold difference between the group means". Furthermore, the specification describes studies in which markers, such as MPIF-1 and TNF-R1, are elevated two fold or more in sepsis patients in comparison to control samples (See Examples, e.g. paragraph [0196])

With respect to new claim 109, "wherein an elevation in concentration of MPIF-1 in the test sample of about four fold relative to the reference concentration is indicative of the presence of severe sepsis in said human" is fully described in the specification. For example, paragraph [0196] of the specification describes that MPIF-1 levels are elevated four fold in sepsis patients as compared to sick controls.

Therefore, the written description does provide ample description in sufficient detail of methods to diagnose severe sepsis as described in the claims. Giving the explicit description

provided by the specification, one skilled in the art would recognize that Applicants had possession of the claimed invention.

Based on the reasons provided above, withdrawal of the rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.

CONCLUSION

Applicants submit that this paper fully addresses the Final Office Dated June 1, 2009, and respectfully requests that the Examiner advance the application to issuance. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned attorney at (650) 849-3017.

FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 36671-747.201).

Respectfully submitted,
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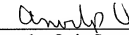
Date: July 7, 2009 By: 
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